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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,836	01/22/2004	Terry L. Riss	341.029US1	5868

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EXAMINER

MARTIN, PAUL C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,836	<b>Applicant(s)</b> RISS ET AL.	
	<b>Examiner</b> Paul C. Martin	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 15-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/26/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-84 are pending in this application, Claims 15-84 were withdrawn as being directed toward non-elected inventions.

Claims 1-14 were examined on their merits.

The rejection of Claims 1-14 under 35 USC § 112, first paragraph has been withdrawn as the Applicant's arguments regarding the detection of enzymes were found to be persuasive.

The rejection of Claims 1-14 under 35 USC § 112, second paragraph has been withdrawn as the Applicant's arguments regarding the measurement of quantifiable amount of enzyme and cofactor were found to be persuasive.

The rejection of Claims 1, 4 and 5 under 35 USC § 102 (b) has been withdrawn due to the Applicant's amendment.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 1-5, 8-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant *et al.* (2002).

Grant *et al.* teaches a method to detect the presence of dipeptidyl aminopeptidase (DAP) and leucine aminopeptidase (LAP) by contacting a sample containing LAP and DAP sequentially with a reaction mixture and wherein DAP and LAP are contacted with the reaction mixture simultaneously, wherein a reaction mediated by DAP yields a fluorescent product, a reaction mediated by LAP yields a fluorescent product and a reaction mediated by both enzymes yields a fluorescent product thereby detecting the presence of both enzymes and substrate (Pg. 535, Fig. 4).

It is inherent in the method taught by Grant *et al.* that the fluorescent product derived from the reaction of LAP and DAP is also necessarily a luminescent product. The Oxford English Dictionary defines luminescence as, "1. Luminescent condition or quality, 2. Light, or a glow, emitted by a luminescent (cool) object or surface". As luminescence is undefined in the instant disclosure, the Examiner has applied the broadest, reasonable interpretation of the term and deems that a fluorescent product is in fact, a species of luminescent product.

***Claim Rejections - 35 USC § 103***

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant *et al.* (2002) in view of Bronstein *et al.* (US 6,586,196 B1).

The teachings of Grant *et al.* were discussed above.

Grant *et al.* does not teach wherein the first molecule is a co-factor for the first enzyme mediated reaction, wherein the second molecule is a co-factor for the second enzyme-mediated reaction.

Grant *et al.* does not teach wherein the sample is a cell lysate, or wherein the sample is contacted with the reaction mixture for the first reaction before the reaction mixture for the second reaction or wherein the sample is contacted with the reaction mixture for the second reaction before the reaction mixture for the first reaction.

Bronstein *et al.* teaches a method to detect the amount of activity of first enzyme for a first enzyme-mediated reaction and a second enzyme for a second enzyme-mediated reaction, comprising:

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a) contacting a rodent cell lysate with a reaction mixture for the first reaction and for the second reaction, wherein a reaction mixture mediated by the first alkaline phosphatase yields a luminogenic product, and wherein a reaction mediated by the second luciferase yields both a luminogenic product; and b) detecting the activity of the first and the second enzymes in the sample (Column 20, Lines 20-38, Fig. 1 and Column 23, Claim 1).

Bronstein *et al.* teaches wherein the activity of the first and second enzymes is detected sequentially by contacting the lysate sample with the reaction mixture for the first reaction before the reaction mixture for the second reaction (Column 20, Lines 20-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method to detect the presence of dipeptidyl aminopeptidase (DAP) and leucine aminopeptidase (LAP) through fluorescent substrates as taught by Grant *et al.* with the method to detect Alkaline phosphatase and luciferase in a cell lysate through bio- and chemi-luminescent substrates as taught by Bronstein *et al.* because it would have been recognized that the methods are equivalents. One of ordinary skill in the art would have been motivated to combine these two methods because it would enable the simultaneous detection of two types of enzymes and substrates without high background interference caused by endogenous fluorescent components found in many test samples.

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There would have been a reasonable expectation of success because both methods are drawn to similar assays of detecting multiple enzymes in a single reaction mixture, via an enzyme/substrate light generating reaction.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1655

08/16/06

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER